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PATENT
Customer No. 22,852
Attorney Docket No. 3260.0028-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	
	)	
Thomas J. GRADDIS et al.	)	
	)	
Serial No.: 09/904,536	)	Group Art Unit: 1647
	)	
Filed: July 16, 2001	)	Examiner: L. Spector

For: METHODS OF USING MUTANT FLT3-LIGAND POLYPEPTIDES (As Amended)

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Office action mailed May 21, 2004, and pursuant to 37 C.F.R. § 1.111, Applicants submit the following remarks.

In the Office action, the Examiner required restriction under 35 U.S.C. § 121 to one of five groups as follows:

I. Claims 33-41, 69-80, 111-132, 134, and 135, drawn to expansion of hematopoietic cells *in vivo* or *in vitro*, including transplantation of hematopoietic cells.

II. Claims 42, 81-90, 136, and 137, drawn to methods of treating infection.

III. Claims 43, 91-93, and 96, drawn to treatment of myelodysplasia.

IV. Claims 45, 97-101, 104, 133, 138, 140, and 141, drawn to treatment of cancer, including leukemia.

V. Claims 52-55, 105-110, and 139, drawn to augmentation of an immune response to a bacterial or viral vaccine.

Applicants elect with traverse, Group I, claims 33-41, 69-80, 111-132, 134, and 135, drawn to expansion of hematopoietic cells *in vivo* or *in vitro*, including transplantation of hematopoietic cells.

A restriction requirement may be proper when the inventions are "independent and distinct" as claimed. 35 U.S.C. § 121; 37 C.F.R. § 1.142(a); emphasis added. Here, the Office asserts only that the inventions are distinct and, therefore, has failed to demonstrate that the claims of Groups I-V are independent and distinct, as required by 35 U.S.C. § 121.

Furthermore, the Office has not demonstrated that the claimed inventions are distinct from one another. The Office asserts that

> The inventions are distinct, each from the other because:
>
> It has been established that the products used in each invention are patentable over the prior art, see patent 6,291,661. However, each invention above requires a separate search of the art with respect to enablement. The etiology of each condition must be considered, including whether hematopoietic progenitor cells are affected or would be expected to be beneficial for that particular condition. Art regarding one of the above treatments will not reveal art as to the others. Accordingly, each invention is distinct from the others, and a search of all the above inventions would be burdensome.

(Office Action, p. 3.)

According to the M.P.E.P., however, "[t]he term 'distinct' means that two or more subjects as disclosed are related, for example, as combination and part (subcombination) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER (though they may each be unpatentable because of the prior

art)." M.P.E.P. § 802.1; emphasis in original. Section 806.05 of the M.P.E.P. also lists several categories of inventions that can be considered distinct. The Office has not demonstrated that any of the pending claims are "distinct," as set forth in the M.P.E.P. Rather, the Office merely asserts that each invention will require a separate search of the art with respect to enablement. This is not the test to determine whether claims are distinct. Accordingly, for at least this reason, the restriction requirement should be withdrawn.

Furthermore, section 803 of the M.P.E.P. states that "[i]f the search and examination of the entire application can be made without serious burden, the examiner must examine it on the merits . . . ." M.P.E.P. § 803 (emphasis added). Applicants respectfully point out that the Office has not demonstrated the serious burden of examining all of the pending claims together, particularly here, where all the claims are commonly classified in the same class (514) and subclass (2). Therefore, the pending claims should be examined together to avoid unnecessary delay and expense to Applicants and duplicative examination by the Patent Office.

Finally, Applicants' amendments did not necessitate the current restriction requirement. The Office required a previous restriction requirement in September 2002. The Examiner asserts that since that time, the claims have expanded to include numerous different methods of using the flt3-L muteins, giving rise to this current restriction requirement. (Office Action, p. 2.) However, Applicants' earlier claims covered subject matter that the Office now asserts is distinct. For example, the claims of Group II are drawn to methods of treating infection; the claims of Group III are drawn to methods of treating myelodysplasia; and the claims of Group IV are drawn to methods of treating cancer, including leukemia. Those method claims overlap with at least the subject matter of original claim 45, which was directed to a method of

treating a pathological condition, including HIV infection, myelodysplasia, breast cancer, lymphoma, small cell lung cancer, multiple myeloma, neuroblastoma, acute leukemia, testicular cancer, and ovarian cancer. Thus, if the claimed subject matter is independent and distinct, the Office could have, and should have, made this restriction requirement earlier in prosecution. Requiring restriction now, when substantial time has passed, creates unnecessary delay and expense.

In view of the foregoing remarks, Applicants respectfully request the examination on the merits of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: July 1, 2004

By: 

Timothy B. Donaldson
Reg. No. 43,592
(571) 203-2712